

Exhibit 8



January 24, 1995



SUBJECT: Proposal for New Talc Study

TO: J. Neal Matheson

This recommends that J & J sponsor a new, highly structured epidemiology study focused to examine the possibility that cosmetic talc use can lead to increased risk of ovarian cancer.

Background

Six epidemiology studies of ovarian cancer have included talc use questions and attempted to make correlations between talc exposure and incidence of ovarian cancer. In each case, this hypothesis had a very low odds ratio (< 2.0). However, the possibility that there is a stronger association led to a study specifically focused on talc use on the perineum and ovarian cancer.

Harlow, et al (1992) reported an overall odds ratio of 1.5, but also identified a high application rate subset of subjects which had a 2.8 OR. Harlow described this group as having a threefold risk of getting ovarian cancer.

At the FDA/IS RTP workshop last January, Harlow presented his work in a peer reviewed forum. The methodology and validity of his conclusions were most rigorously challenged by Dr. Ernst Wynder, a highly respected epidemiologist and a founder/President of the American Health Foundation.

Following the workshop, Dr. Wynder approached me to ask if J & J would be willing to sponsor better research on the subject. I responded that we might if the research brought new information to the field. Conducting one more routine epidemiology study was of no interest to us.

Wynder responded in October that he was ready to meet to discuss a potential study design. John Hopkins and I met with the group and upon detailed review of the protocol are impressed by the proposed study. Since then, I've had feedback from Marjorie, Bill Ashton, and Steve Phillips. We believe it is a well-controlled, potentially significant study which should replace all others as the definitive treatise on this issue (complete proposal attached).

What we will learn

The study will more comprehensively study the possibility by:

1. Carefully evaluating the epidemiology of controls (characteristics of women who use talc powders and why).
2. Obtaining detailed information on the duration and frequency of perineum exposure and the type of powder used.

3. Considering the latency period between exposure to talc and the diagnosis of ovarian cancer.
4. Considering the woman's history of tubal ligation.
5. Adjusting statistically for the major known risk factors for ovarian carcinoma.
6. Considering the difference in use of talc products pre- and post-1976. This should clarify the possibility that "asbestos contaminated" talc reported to have been on the market prior to 1976 was a causative factor.
7. Minimizing response bias by reducing "risk bias" and recruiting more appropriate controls.
8. Assessing potential occupational exposure to talc.

All these improvements over previous studies will clearly provide more specific, projectable results.

Possible Outcomes

J & J, as a sponsor of this study, will have the opportunity to participate in some aspects of the study design. We will not control the conduct of the interviews, the results analysis, or potential publication of the results. (Detailed aspects of our involvement and sharing of findings will be worked out after agreement to proceed.)

Obviously, the study could prove the expected - no correlation - or, the unexpected - one or more correlated aspects. We should expect any result to be published.

Cost and Timing

The study is expected to require 2+ years to complete and report 171 cases and 171 controls. The proposal shows a start date of March 1, 1995 and completion late 1997.

Costs proposed (we have not negotiated yet) by AHF are as follows:

3/1/95 to 2/28/96	\$176,911
3/1/96 to 2/28/97	\$183,988
3/1/97 to 12/31/97	<u>\$ 37,754</u>

Total \$398,653

There will be J & J manpower costs associated with study design, monitoring, and reporting.

J & J History with AHF

We have considered Dr. Wynder to be a friend through contact on previous issues. McNeil Consumer has sponsored epidemiology work by AHF. Their performance was excellent, the findings did not support the hypothesis.

Suggested Next Steps

- Your agreement in principle to proceed
- Executive review of study plans presented by Dr. Wynder and study team
- Negotiations of cost and J & J involvement details
- Final agreement/signed proposal
- Study design finalization
- Begin study by mid-year 1995

This requests your approval to proceed in principle and schedule a review with AHF.

Donald F. Jones

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attachment

cc: C. Hammes
J. Hopkins
J. Leebaw
M. McTernan
J. O'Shaughnessy
K. Schroeder
W. Slivka

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